REMARKS

In the Office Action of February 9, 2009, the Examiner rejected claims 9-11, 13-16 and 20-28 under 35 U.S.C. 112, first paragraph, for lack of enablement. The Examiner objected that the specification does not reasonably provide enablement for a method for protecting a mammal against all bacterial infection by submucosal injection of any live bacterial vaccine. The Examiner has asserted, even though a number of live attenuated bacterial vaccines were available, Applicants' arguments are not fully persuasive because the scope of the invention is alleged to be broader than that limited number of vaccines available at the time the application was filed, and further that the vaccines are host specific, while, as claimed, the invention encompasses the use of any live bacterial attenuated vaccine for any mammal. The Examiner concluded that undue experimentation is required "[s]ince the submucosal injection of any live attenuated bacterial strain as a vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and vaccination outcome base[d] upon the immune protection the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue."

The rejection under 35 U.S.C. 112, first paragraph, for lack of enablement is respectfully traversed. Applicants established in the Appeal Brief filed April 1, 2008, that the preparation of live attenuated vaccines was well known in the art at the time the present application's priority case was filed. A sampling of 23 publications published prior to the filing date of the priority application or, in the case of patents, applications with priority early than that of the present application, fully established that the ordinary practitioner at the time of Applicants' filing was fully capable of preparing live attenuated bacterial vaccines. (see Appeal Brief, Table I). Applicants further provided in the specification three working examples of submucosal administration with four different live attenuated bacterial vaccines to two different host species. The description of these procedures fully enabled the skilled practitioner to carry out submucosal administration of a live attenuated bacterial vaccine.

Determining the effectiveness of reducing abscesses at the site of vaccine administration is completely within the skill of the art. This is described in the examples. Clearly the ordinary

practitioner could determine whether or not the administration of a known, effective quantity of a live attenuated bacterial vaccine results in the formation of abscesses that are reduced in size when the vaccine is administered submucosally by comparison with abscesses formed when administering the same vaccine intramuscularly.

The claimed invention is the discovery that the formation of abscesses is reduced using submucosal administration using known vaccines. It is not the development or determination of the effectiveness of new vaccines.

Claim 9, for example, is directed to a method for reducing the amount of adverse reactions in a mammal at the injection site when administering a live attenuated bacterial vaccine. The claimed method comprises, simply, administering the vaccine submucosally. The vaccine used is one that causes abscess formation when administered intramuscularly. To determine whether or not the method can be practiced with any particular vaccine requires the skilled practitioner to merely determine whether or not the amount or size of abscesses at the injection site are reduced when the vaccine is administered submucosally compared with when it is administered intramuscularly.

A claim satisfies the enablement requirement if the specification enables a skilled artisan to make and use the claimed invention without "undue experimentation." Applicants meet all the requirements set forth in In re Wands, referred to by the Examiner. In finding enablement, in that case, the Court noted: (1) the specification provided guidance for practicing the invention, (2) the specification provided working examples, (3) the level of skill in the art was high, (4) the methods needed to practice the invention were well known in the art, (5) the nature of the technology involved screening to identify antibodies with the desired characteristics. In re Wands 858 F.2d at 739-740, 8 USPQ2d at 1404-406. All of these "Wands" criteria are met. Moreover, item (5), regarding the nature of the technology involving screening antibodies for desired characteristics, is perfectly analogous to screening known live attenuated bacterial vaccines by the ordinary practitioner according to the methods taught in the specification to determine whether or not submucosal administration is advantageous, as presently claimed.

It is further noted that the recognized unpredictably of the vaccine art is not an issue. The

ordinary practitioner, to practice the claimed invention, would be using a live attenuated bacterial vaccine, i.e., an immunogenic composition that is known to have vaccine properties. There is no requirement that it be a new vaccine. By using the present invention the ordinary practitioner will be intending to reduce the negative impact of abscess formation on the administration of the vaccine by the method of administering the vaccine submucosally.

Claims 9-11, 13-16 and 20 stand rejected under 35 U.S.C., first paragraph, for failing to comply with the written description requirement. The Examiner has alleged that the introduction of the terms, "replicate at the injection site," introduces new matter.

Applicants respectfully submit that the replication of bacteria at the injection site resulting in abscesses is supported in the specification on page 2, lines 12 and 13, where it is stated that "the bacterium often replicates at the injection site to such a level that the abscess even bursts." It is believed clear from this, and certainly well known to the practitioner, that the use of live bacterial vaccines results in replication at the injection site. However, in order to advance the prosecution of this application, and without disclaimer, Applicants have amended claim 9 to revert the language of the claim to be the same as it was prior to the amendment filed September 25, 2008, to which the Examiner presently objects. In view of the above, it is believed that claims 9, 10, 13-16, 21, 22 and 25-28 are in condition for allowance.

Claims 11, 20, 23 and 24 have been canceled without prejudice or disclaimer of the subject matter thereof. The cancellation of these dependent claims is made for the purpose of clarifying that the invention is directed to the use of any live attenuated bacterial vaccine.

Should it be believed that a conference would be helpful in advancing the prosecution of this application, the Examiner is invited to telephone the Applicants' attorney at the number below.

Pursuant to 37 C.F.R. § 1.116, Applicants submit that the amendments presented herein are made to i) cancel claims or comply with any requirement of form expressly set forth in a previous Office action, or ii) present rejected claims in better form for consideration on appeal.

Applicants submit that this application is in condition for allowance, and request that it be allowed.

Applicants do not believe that any other fee is due in connection with this filing. If,

however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Respectfully submitted,

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